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PAN MERSEY AREA PRESCRIBING COMMITTEE

PRESCRIBING POLICY STATEMENT

REF: PS185 FINAL

APC BOARD DATE: 28 FEB 2018



Pan Mersey

Area Prescribing Committee

FERRIC MALTOL 30mg hard capsules (Feraccru®)

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The Pan Mersey Area Prescribing Committee recommends the prescribing of FERRIC MALTOL (Feraccru®) following specialist initiation for the treatment of iron deficiency anaemia in adult patients with inflammatory bowel disease.

FOLLOWING SPECIALIST INITIATION

Ferric maltol (Feraccru®) is recommended as an option for treating iron deficiency anaemia (IDA) in patients with inflammatory bowel disease (IBD) only if:

- > an adequate trial of at least **two** oral iron preparations containing ferrous salts (e.g. ferrous fumarate, ferrous sulfate) has been tried and the patient has suffered intolerable adverse effects; **and**
- > haemoglobin is $\geq 95\text{g/L}$ and the patient is being considered for intravenous iron therapy; **and**
- > the patient's IBD is stable; **and**
- > the initial decision to prescribe ferric maltol is made by a specialist in the management of inflammatory bowel disease.

The first course of ferric maltol must be supplied in full by the specialist. After a successful first course of treatment for IDA, the specialist should write to the GP informing them that treatment has been successful and requesting that, if IDA recurs, to issue repeat courses as necessary without the need for specialist involvement, provided the patient's IBD is stable.

Feraccru® is currently only licensed for IDA in IBD; however, there is a pending licence extension for use in IDA. The Pan Mersey APC do not recommend the use of ferric maltol in the management of IDA in patients who do not have IBD. This licence extension will be reviewed according to Pan Mersey APC processes and a prescribing position will be published in the future.

Note: Patients who are not eligible for treatment under this statement may be considered on an individual basis where their GP or consultant believes exceptional circumstances exist that warrant deviation from the rule of this policy. In this situation, follow locally defined processes.

Version: 2.1

Review date: February 2020

(or earlier if there is significant new evidence relating to this recommendation)

FERRIC MALTOL 30mg hard capsules (Feraccru®)

<p>EFFECTIVENESS¹ Feraccru® contains iron in a stable ferric state (Fe³⁺) as a complex with a trimaltol ligand. It is the first oral product to deliver iron in the ferric state and is believed to result in reduced intolerance due to reduce exposure to free iron in the GI tract. In two pivotal phase 3 RCTs of 12 week duration in patients with mild to moderate IDA and stable IBD (n=128), ferric maltol was shown to result in a statistically significant increase in haemoglobin of 22.5g/L from baseline when compared to placebo. The median time to normalisation of haemoglobin was 57 days. In an open label extension study of 48 weeks duration, haemoglobin levels continue to rise to a maximum of 140g/L.</p>	<p>SAFETY² Ferric maltol is contraindicated in patients with hypersensitivity to the active substance or any excipients, haemochromatosis or other iron overload syndromes and in patients receiving repeated blood transfusions. There are limited data on the use of ferric maltol in patient with severe IDA (haemoglobin <95g/L) or active IBD, and its use is cautioned in these patients. The most commonly reported adverse effects were arthralgia and gastrointestinal symptoms, including abdominal pain, reflux, flatulence, rectal haemorrhage, abdominal distension and constipation. There is no evidence that ferric maltol exacerbates symptoms of IBD.</p>
<p>COST³ A twelve week course of ferric maltol 30mg twice daily costs £142.80.</p> <p><i>Comparators:</i> Ferrous sulfate (200mg TDS, 12/52): £9.72 Ferrous fumarate (210mg TDS, 12/52): £10.50 Ferric carboxymaltose [Ferinject®] (IV, 1.5g – 2g): £235.41-£308.46*</p> <p><i>*does not include tariff administration costs. Included for comparison purposes only, product used may differ between Trusts.</i></p>	<p>PATIENT FACTORS² The safety and efficacy of ferric maltol has not been established in the paediatric population and it is not recommended in children. No dose adjustments are required in elderly patients. There is no evidence regarding dosing in patients with renal or hepatic impairment; ferric maltol should be used with caution in patients with these conditions. The manufacturers recommend avoiding ferric maltol in pregnant and lactating women.</p>

PRESCRIBING INFORMATION

The recommended dose of ferric maltol is 30mg twice daily, morning and evening, taken whole on an empty stomach with half a glass of water. Treatment duration will depend on the severity of the IDA, but generally 12 weeks treatment is required. Treatment should be continued until tests demonstrate that iron stores have been replenished.

IMPLEMENTATION NOTES

The initial decision to prescribe ferric maltol must be made by a specialist in the management of IBD, which might include gastroenterologists, specialist non-medical prescribing nurses/pharmacists working in gastroenterology and GPs with a specialist interest. The specialist making the decision to prescribe a first course of ferric maltol is responsible for supplying the complete first course. It is acknowledged that IDA will recur in a significant proportion of patients with IBD. After a successful first course of treatment for IDA, the specialist should write to the GP informing them that treatment has been successful and requesting that, if IDA recurs, to issue repeat courses as necessary. Patients, who have previously been treated with intravenous iron prior to the availability of ferric maltol, can be prescribed this agent provided they meet the criteria. However, patients who have failed to respond to ferric maltol and have required intravenous iron should not be given repeat courses.

REFERENCES

1. London Medicines Evaluation Network Review. Ferric Maltol (oral Feraccru®) for the treatment of iron deficiency anaemia in adults with inflammatory bowel disease (May 2016). Available online: https://www.sps.nhs.uk/wp-content/uploads/2016/06/LMEN_Ferric_Maltol_IDA_IBD_FINAL_May16_v2.pdf (last accessed 06/12/2017)
2. Summary of Product Characteristics: Feraccru 30mg hard capsules (Sheild TX UK Ltd, last updated 09/05/2017). Available online: <http://www.medicines.org.uk/emc/medicine/31722> (last accessed 06/12/2017)
3. NHS Business Services Authority. Dictionary of medicines and devices (dm+d). Available online: <https://apps.nhsbsa.nhs.uk/DMDBrowser/DMDBrowser.do> (last accessed 09/02/2018)